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Topics: COVID-19 , Influenza, General

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Dr Brosseau is a national expert on respiratory protection and infectious diseases and a research consultant with the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota (UMN). ***Dr MacIntyre*** *is Professor of Global Security at the University of New South Wales. She coauthored a separate* ***critique*** *of the Jefferson Cochrane review.* ***Dr Ulrich*** is a UMN assistant professor in the Division of Environmental Health Sciences and a CIDRAP researcher. ***Dr Osterholm*** is CIDRAP director and Regents Professor at UMN.

Two recent publications conclude there are no differences between surgical masks and respirators for preventing person-to-person transmission of infectious respiratory viruses like SARS-CoV-2 and influenza. But these studies are deeply flawed.

One of these is a randomized controlled trial (RCT) by Loeb et al comparing SARS-CoV-2 infections in healthcare workers wearing respirators or masks for care of COVID-19 patients.[1] The other is a Cochrane review by Jefferson et al of mask and respirator studies in households and healthcare settings.[2]

Both are built on the premise that infectious respiratory viruses like SARS-CoV, SARS-CoV-2, MERS-CoV, and influenza are *only* transmitted person to person by large droplets. This is not true. The science is very clear that the predominant mode by which these viruses are transmitted person to person is inhalation of small particles, most of which are around 1 micrometer.[3–13]

COVID-19 and flu are spread by aerosol inhalation

Droplet transmission occurs when someone coughs or sneezes into the eyes, nose, or mouth of someone

nearby. This might happen when a healthcare provider is in close contact with a symptomatic person and perhaps when parents are caring for sick children, but otherwise this is a fairly unlikely event.[14]

People continuously release many particles in a wide range of sizes but most of them are relatively small (around 1 micrometer), when they're breathing, talking, singing—and coughing or sneezing. The smaller particles remain suspended in air for long periods—minutes to hours—and can accumulate over time and easily disperse throughout an indoor space. Numerically, breathing and talking contribute much more than coughing or sneezing to the amount of virus in the air because they occur continuously or very frequently.

SARS-CoV-2 is capable of remaining viable in air for some hours. We know that people with COVID-19 are most infectious just before and as symptoms are developing, so transmission is possible before anyone knows they're infected. Some 30% or more of infected people never develop symptoms but are still infectious.

All of these facts explain why aerosol inhalation is much more likely than droplet transmission. They also explain why infection can occur both near and far from an infected source.

Masks offer little protection

We've discussed cloth and surgical masks in detail elsewhere (see "**Masks-for-all for COVID-19 not based on sound data**" and "What can masks do?" **part 1**). The most important variables are filter efficiency—how well the filter collects particles of all sizes; fit—how well the facepiece prevents leakage around the edges; and breathing resistance—how easy it is to inhale and exhale through the filter.

Some surgical masks have a reasonable filter but exhibit increased particle leakage around the edges because of their loose fit. Without a close fit around the face, a surgical mask cannot limit inward or outward leakage of particles as well as a respirator can.

Surgical masks vary widely in filter material, design, and effectiveness, but most don't have high filter efficiency. The filter tests required by the US Food and Drug Administration are not predictive of surgical mask filter performance, so it's impossible to know which surgical mask filters can collect small particles.[15,16] Surgical masks are not expected to fit tightly against the face, so they have considerable inward and outward leakage of particles.

A surgical mask might prevent large droplets from contacting the nose and mouth but offers no protection from someone else's smaller inhalable particles. And it will not prevent such particles from being emitted around the edge of the mask.

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Cloth is not designed to collect particles and has a very low collection efficiency for smaller particles and thus offers little protection for the wearer or nearby people. It's possible to make a cloth mask more efficient by increasing the thickness or number of layers, but that will also increase the breathing resistance, which decreases comfort.

Respirators prevent aerosol inhalation

Respirators are not masks. The correct term for a device approved by the National Institute for Occupational Safety and Health (NIOSH) to prevent inhalation of hazardous materials is "respirator" (and not "respirator mask").

Respirators have very effective filters and are designed to fit most faces. A respirator filter is easy to breathe through, because it's made of a fibrous electret material that has low breathing resistance. Any type of respirator filter approved by NIOSH—N, P, R, 95, 99, 100—will be effective at collecting human-generated aerosols.

Although designed to protect the wearer from inhaling hazardous aerosols, an N95 filtering facepiece respirator (FFR) will also prevent the outward leakage of particles produced by the wearer when breathing, talking, singing, etc.[17,18]

In workplaces, employers must test the fit of a respirator on every employee to ensure

Fit-testing.
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they're getting the required level of protection. An N95 FFR requires a fit factor (outside particle concentration divided by inside concentration) of 100. The 100 fit factor is a safety factor of 10 multiplied by the respirator's assigned protection factor (APF) of 10. An APF of 10 means that an N95 FFR is expected to reduce the outside concentration of infectious particles by 10 times. A safety factor is used because fit-testing isn't exactly like wearing the respirator in the real world and ensures that the respirator will fit during work activities.

It is impossible to achieve a fit factor greater than 5 to 10 with a surgical mask, because they don't fit tightly and aren't expected to.[16,19,20] Even if a surgical mask has a good filter, it will have substantial leakage around the edges. A fit factor of 5 or 10 is much less than the 100 fit factor expected when fit-testing an FFR. A surgical mask that gets a fit factor of 5 or 10 during fit-testing is going to provide very little inhalation protection and will not limit the outward leakage of small particles from the wearer.

Cloth masks can rarely achieve a fit factor greater than 1, which means they don't fit well at all, because a fit factor of 1 means that the inside and outside concentrations of particles are the same.

Where did the assigned protection factor of 10 for an FFR come from? The Occupational Health and Safety Administration (OSHA) reviewed studies of respirator performance conducted in workplaces to determine the most likely level of protection that a half-facepiece respirator like an FFR could achieve.[21] The APF of 10 for an FFR is a very conservative estimate of performance, representing the level of protection that was achievable for at least 95% of all workers exposed to hazardous aerosols in a range of workplaces.

Trial of masks vs respirators flawed

The RCT by Loeb et al[1] has many flaws. First, this study was unethical by putting the healthcare workers wearing surgical masks at risk of infection by aerosol inhalation.

Second, this study's stated goal was to assess the role of masks versus respirators in preventing *droplet transmission* of SARS-CoV-2, but that research goal is not aligned with the purpose of a respirator, which is *not* to protect people from liquid sprays. That's what face shields or full facepiece respirators are for.

Third, the study authors defined equivalence as being less than twice as bad. Healthcare workers were not consulted about whether they would accept a product that would meet this definition of "equivalence."

Not only did this study unethically put healthcare workers at risk for aerosol transmission of SARS-CoV-2, but it was also a large waste of time and resources given what we know about the superiority of respirators in both limiting and protecting the wearer from aerosol transmission. We do not need an RCT of respirators in any workplace, because scientists have measured their real-world performance, and OSHA has determined that a fit-tested N95 FFR will reduce inhalation exposure to infectious particle concentrations by at least 10 times.

Hazardous infectious aerosols in a healthcare setting are no different than the hazardous aerosols found in workplaces. A respirator that protects workers in an industrial setting will also protect healthcare workers from SARS-CoV-2 and other infectious respiratory viruses.

Respirators must be worn for *all* exposures

Another major flaw of the Loeb et al RCT was the intermittent use of respirators, which has been proved to be not effective.

The only RCT to compare continuous and intermittent use of N95 FFRs shows that they protect healthcare workers only when they're worn continuously in the workplace.[22] This supports aerosol transmission of respiratory infectious diseases and the ubiquitous risks faced by healthcare workers.

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Loeb et al compared masks to respirators in healthcare settings during the pandemic, but workers were required to wear them only when providing direct care to suspected and confirmed COVID-19 patients. Because the virus is airborne and can remain suspended in the air for hours even when an infected person is gone, there are a number of other opportunities for exposure and infection in healthcare settings.

In fact, studies have found that infection rates for healthcare workers wearing respirators in intensive care units with COVID-19 patients are much lower than in other healthcare settings.[23–25] This fact alone demonstrates that respirators and other measures such as negative-pressure rooms will protect healthcare workers from SARS-CoV-2 aerosols.

It takes only one short encounter with an infectious person to be infected, given the likely very low infectious dose of SARS-CoV-2.[26–28] Every unprotected exposure to someone whose infection status is unknown (patients, coworkers, visitors, etc) may transmit the virus by aerosol inhalation.

A study that does not evaluate all likely exposures throughout the workday, or assumes that healthcare workers can identify all potential exposures, cannot make accurate conclusions about the effectiveness of a respirator worn only part of the time.

What about respirators for the public?

Even without fit-testing, respirators are more likely to provide a higher level of protection than a cloth or surgical mask. Brosseau[29] demonstrated this with an N95 FFR tested on untrained volunteers. While only 3% to 10% of the wearers were able to achieve a fit factor of 100, a strong majority (76% to 86%) were able to achieve a fit factor of 10.

A 2021 case-control study compared SARS-CoV-2 positivity for members of the public reporting some use of masks or respirators with those reporting no use.[30] This study found that wear time was a significant factor in reducing the likelihood of infection. The likelihood of testing positive for wearing a mask or respirator some of the time was 71%, most of the time was 55%, and all of the time was 44%. However, the likelihood of testing positive was much lower for those wearing a respirator (17%) than a surgical mask (34%), compared to not wearing anything (wear time was not reported for this analysis).

It's important to note that cloth masks did not significantly affect the likelihood of testing positive. The confidence interval for surgical masks was very wide—3% to 90%—which suggests that some surgical masks might provide some degree of protection. As discussed above, however, they don't fit well, and it's impossible to know whether any particular surgical mask has a good filter. Any protection provided by a mask will be much less than that offered by a respirator.

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Using the Centers for Disease Control and Prevention (CDC) contact tracing time of 15 minutes as a baseline for "time to infectious dose," Brosseau et al developed a table in a 2021 **CIDRAP commentary** demonstrating the impact of the source and receptor wearing different combinations of masks and respirators. If the source (infected person) is not wearing anything, the receptor (uninfected person) would be likely to receive an infectious dose after 20 minutes wearing a cloth mask, after 30 minutes wearing a surgical mask, after 1¼ hours wearing a non–fit-tested respirator and after 2½ hours wearing a fit-tested respirator. If both are wearing a surgical mask, the time extends to 1 hour. Only if both are wearing a respirator does the time to an infectious dose extend to many hours.[31]

KN95 respirators, if authentic, should have filter efficiency equivalent to that of a NIOSH-approved N95 FFR. Their ear loop design, however, makes it difficult to obtain a tight fit.

Cochrane reviews can be wrong

The Cochrane review by Jefferson et al[2] states that respiratory viruses spread as follows: "People infected with a respiratory virus spread virus particles into the air when they cough or sneeze. Other people become infected if they come into contact with these virus particles in the air or on surfaces on which they land."

This is the classic definition of droplet transmission, which focuses solely on symptomatic coughing or sneezing that produce large droplets propelled into the face of someone nearby. This review was also focused on contact transmission, which has been ruled out for SARS-CoV-2 by scientists and public health authorities like the CDC.

There is no mention of airborne or aerosol transmission, the former being defined as inhalation of "droplet nuclei" at long distances from a source, and the latter representing a more up-to-date understanding of infectious particle inhalation both near and far from a source. An RCT by MacIntyre et al showed that even for infections assumed to be droplet transmitted, N95 FFRs prevent infection, while surgical masks do not.[32] This again points to the droplet paradigm being incorrect.

The Cochrane reviewers apparently recognize that asymptomatic transmission is a possibility for influenza. For example, they critique a household study for failing to recognize and follow up on asymptomatic influenza-like illness.[33] They note that at least two thirds of the healthcare workers with positive serology for influenza did not have fever or symptoms, and thus were asymptomatic in a 2009 RCT comparing influenza in healthcare workers wearing surgical masks or respirators.[34] Asymptomatic transmission accounts for approximately 24% of person-to-person spread of SARS-CoV-2.[35]

The Cochrane review must be considered in the context of the authors' biases.

But recognizing that people may be possibly asymptomatic doesn't provoke the authors to reconsider the transmission modes of SARS-CoV-2 or implications for the effectiveness of masks or respirators worn only when patients or household members are exhibiting symptoms.

The Cochrane review must be considered in the context of the authors' biases. The authors focused on studies in healthcare settings that compare the "standard of care" for droplet transmission—ie, surgical masks—with an N95 or P2 FFR. However, for scientists who understand that aerosol transmission is an important and most likely the primary mode of transmission for respiratory viruses, a surgical mask would never be the standard of care.

The Cochrane review has a number of serious methodological flaws, as well.

For example, the authors included two healthcare trials in their analysis of studies comparing the use of surgical masks to no masks in preventing household transmission of influenza. It is not clear how these two settings might be considered similar, as one involves households where people might wear a mask voluntarily, and the other is a workplace where employees are expected to adhere to droplet precautions.

The exposure scenarios are also very different. The latter involves many more relatively short contacts with potentially infected people in potentially better ventilated spaces (although many spaces in healthcare settings are not well ventilated), while the former involves very few but potentially much longer contacts in spaces with low ventilation.

Jefferson et al did not consider the impact of exposure on the outcomes or effectiveness of the different interventions. They did not address the number, length, and nature of contacts and did not consider the possibility for transmission during unprotected periods for either the community or healthcare studies reviewed. The authors appear to believe that people in households and healthcare settings are capable of identifying when an exposure might occur, failing to recognize that pre- or asymptomatic transmission is a strong possibility for respiratory viruses.

As well, the authors did not include RCTs in surgical settings or the reviews and meta-analyses (Cochrane and otherwise) that found no difference in surgical wound infection rates with or without masks.[36–38] Those are conveniently ignored, as they have been by most of the medical community.

The Cochrane review authors incorrectly combined studies where people wore masks or respirators infrequently with those where they were worn all the time. A careful examination of the studies where healthcare workers were required to wear the intervention throughout the day shows that respirators are more effective than surgical masks at preventing infection from respiratory viruses.[32]

The Cochrane review authors incorrectly combined studies where people wore masks or respirators infrequently with those where they were worn all the time.

The Cochrane review authors also fail to recognize that most of the healthcare RCTs do not have a control group—that is, a no-mask group—against which the surgical mask and respirator groups could be separately compared. A healthcare study with a non-randomized control group and full-time wearing of the interventions has clearly demonstrated that respirators are superior to surgical masks in preventing respiratory illness.[32] But this study was ignored and its findings diluted by combining it with dissimilar

investigations.

Science should seek to understand, not obfuscate

The droplet dogma for infectious respiratory viruses like SARS-CoV-2 and influenza is a creed that has outlived its usefulness and is no longer supported by any current data.

Medical knowledge for patient care is frequently updated by new scientific findings leading to new drugs, devices and procedures. But there are some medical practices, like surgical masks, and beliefs, like droplet transmission, that seem impossible to change despite a vast scientific literature that points to aerosol inhalation as the primary mode of transmission for respiratory viruses and respirators as the only effective personal protective equipment for exposure to such viruses.

The Cochrane review authors conclude that "The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks." We agree with this finding, but not for the reasons stated in this review. Surgical or medical masks have very ineffective filters and do not fit and thus will not limit outward emission of human-generated aerosols, nor will they protect the wearer from inhalation of such aerosols. Respirators, whether fit-tested or not, are the better option for the public for protecting themselves and others around them from respiratory viruses.

The Cochrane review authors concluded that there is "no clear difference between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection." The authors do not appear to be bothered by the fact that surgical masks are supposedly effective in healthcare settings but not in community (household) settings. They make no effort to explain this discrepancy.

It's well past time to move past that debunked dogma.

We strongly disagree with their conclusion about no difference between surgical masks and respirators, for the reasons discussed above. But respirators are not necessarily the only effective method for preventing or minimizing aerosol transmission of infectious respiratory viruses in healthcare settings. Instead, more attention must be given to source and pathway controls, such as improving ventilation and air cleaning in clinics, patient rooms, and spaces shared with coworkers.

It may be appropriate to require universal use of respirators by all workers in healthcare settings (and possibly patients, as well) when there are high community rates of respiratory viruses. Respirators can also play a role in limiting transmission during close or prolonged contacts with patients. Without regular and rapid testing of all patients to identify those who may be infected but asymptomatic, however, it may be difficult to predict all potential exposures.

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The Loeb et al RCT and the Jefferson et al Cochrane review are part of ongoing efforts by physicians and infection-control professionals to promote the droplet transmission dogma, which has been disproved and invalidated by data demonstrating that people generate small inhalable infectious particles all of the time, that these particles remain in the air for long periods, and that respiratory viruses can remain viable in air for many hours.

It's well past time to move past that debunked dogma.

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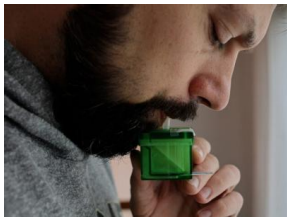

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